

REMARKS**Status of the Claims**

Claims 1, 3-8, 10-25, 27-49 and 52 are currently pending. Claims 29-47 are withdrawn as being drawn to nonelected inventions. Claims 1, 3-8, 10-25, 27, 28, 48-49 and 52 have been examined on the merits and rejected. In this Response, no claims are amended. Accordingly, claims 1, 3-8, 10-25, 27, 28, 48-49 and 52 remain pending and subject to further examination. Reconsideration of the claims in view of the following comments is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1, 3-8, 10-25, 27, 28, 48-49 and 52 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Craig (US 5,792,943, hereinafter “Craig”) in view of Goedert (US 4,935,040, hereinafter “Goedert”).

Regarding independent claims 1, 27 and 28, Craig allegedly discloses a gas chromatograph column (col. 12, l. 54 - col. 13, l. 1), which column comprises more than two lid layers and more than one channel layer (col. 4, l. 41-47 and fig. 6a-6b), wherein each of said layers comprises a compact material (see “substrate material”, col. 5, l. 1-8) suitable for gas chromatography (col. 12, l. 54 - col. 13, l. 1), said channel layers comprise microfabricated channels on both sides (col. 17, l. 8-11, and fig. 6a-6b) and a side of said lid layers form at least four capillaries (“channel 260”, “channel 262”, fig. 6a-6b and col. 4, l. 41-47), said at least four capillaries are connected to each other through a hole in said channel layer to form an integrated capillary (“conduit means 272”, fig. 6a-6b), said integrated capillary is connected to outside atmosphere on both ends via holes on two outmost lid layers (implicitly disclosed in fig. 6a-6b) to serve as an inlet and an outlet (“aperture 270”, “aperture 278”, fig. 6a-6b).

The Office acknowledges that Craig fails to explicitly disclose a gas chromatograph column wherein said lid layers and channel layers are discrete lid and channel layers. To cure this deficiency of Craig, the Office cites Goedert, which allegedly discloses a miniature gas

chromatography column (abstract) comprising a plurality of discrete lid and channel layers (fig. 1) in order to form a unitary body having aligned chromatographic micro-columns (col. 4, l. 61-64) and “to allow separate fabrication of said lid and channel layers (implicitly disclosed)”. The Office argues that “it would have been obvious at the time of the invention to combine the discrete lid and channel layer teachings of Goedert with the gas chromatograph column of Craig to allow separate fabrication of the lid and channel layers, thereby increasing the scale and ease of production of such gas chromatograph columns”. Further, the Office argues that “while Craig fails to explicitly disclose discrete lid and channel layers, it would have been obvious to one having ordinary skill in the art at the time of invention to separate the lid and channel layers of Craig, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (MPEP 2144.04, Section V, Part C)”.

Applicants respectfully traverse this rejection for the reasons set forth below.

The obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the scope and content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter must be considered. *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). In appropriate circumstances, a single prior art reference can render a claim obvious. However, there must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion. This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000) (citations omitted; emphasis added).

As discussed previously, Craig discloses a planar separation column device that includes complementary microstructures formed in a planar foldable substrate (abstract, Figs. 3-13). Craig specifically teaches that “[i]t is a primary feature of the present invention to construct the integrated assembly from a planar substrate having at least first and second component sections separated by a linear fold means, wherein said substrate is comprised of a material that is ductile in the region of

the linear fold means and substantially inextensible in the regions defined by the component sections” (col. 4, lines 3-9, emphasis added). Craig explains that “[t]he fold means constrains the co-location of the microstructures with extreme accuracy due to the inextensibility of the substrate with respect to the fold axis” which facilitates joining “the complementary microstructures... with precise alignment” (col. 4, lines 33-37, emphasis added). Craig further states:

A “multilayer” integrated assembly refers to an assembly formed from a foldable substrate whereby the component sections are subject to closure so as to form at least two bonded layers. A particularly preferred multilayer integrated assembly includes n component sections [*sic*] and (n-1) linear fold means, wherein n equals three or more, wherein the component sections are closed upon one another in what is referred to as a “Z-fold configuration” upon performing a folding action along the (n-1) fold axes of said (n-1) linear fold means.

(Craig at col. 11, lines 47-56, emphasis added).

Thus, Craig expressly teaches that the idea of using a continuous foldable substrate is central to the invention because it facilitates precise alignment of the microstructures.

Goedert discloses a miniature gas chromatography device wherein wafer pairs are first laminated together to form microchannels (Fig. 2, col. 4, lines 23-24). After that, a plurality of wafer pairs are stacked and laminated together to form a unitary body and to align a corresponding plurality of chromatographic microchannels (Fig. 1, col. 4, lines 61-65). The microchannels formed within each wafer pair may be linked by connecting channels aligned pairwise to lead perpendicularly through the laminated wafer pairs (Fig. 1, col. 5, lines 3-6). Thus, in Goedert, the microfabricated channels are formed within each wafer pair (i.e., the groove is always on one side of a wafer), which is different from the chromatograph column of claim 1, for example, wherein a single channel layer has grooves on both sides that can form microchannels with other channel layers or lid layers.

The Office makes two principal arguments: (1) a person skilled in the art would have been motivated to combine the teachings of Craig and Goedert “to allow separate fabrication of the lid and channel layers, thereby increasing the scale and ease of production of such gas chromatograph columns”; and (2) “it would have been obvious to one having ordinary skill in the art at the time of

invention to separate the lid and channel layers of Craig, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art”. We shall address each of these arguments in turn.

“Allowing separate fabrication of the lid and channel layers”

The Office asserts that a person skilled in the art would have been motivated to combine the teachings of Craig and Goedert “to allow separate fabrication of the lid and channel layers, thereby increasing the scale and ease of production of such gas chromatograph columns”. However, as discussed previously, there are multiple reasons why such a combination does not make sense.

As an initial observation, Goedert does not teach or even suggest that the use of discrete layers allows separate fabrication of the lid and channel layers, thereby increasing the scale and ease of production of such gas chromatograph columns. Although the Office seems to intimate that Goedert “implicitly discloses” this rationale, a careful reading of Goedert fails to reveal any hint of it. Instead, the Office merely tries to use impermissible hindsight to come up with a semblance of a rationale solely to fit the square peg of Craig into the round hole of the present invention.

As noted above, Craig and Goedert describe conceptually different structural arrangements. In Craig, the “layers” are sections of a continuous foldable substrate that are separated by ductile material that permits precise alignment of the microchannels. In Goedert, the layers are discrete structural elements that are laminated in a pairwise manner to create enclosed microchannels. Since the principles of operation are completely different, a person skilled in the art could not possibly have been motivated to combine the teachings of Craig and Goedert with a reasonable expectation of success. Moreover, it is apparent that modifying the device of Craig in a manner consistent with the present application would produce a result that is contrary to what Craig is trying to achieve. As discussed above, the device of Craig aims to achieve precise alignment of the microstructures by providing a rigid foldable substrate. Splitting the substrate into discrete units would clearly defeat this purpose. It is well settled law, however, that if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01, citing *In re Gordon*, 733 F.2d

900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

“Constructing a formerly integral structure in various elements”

The Office argues that “while Craig fails to explicitly disclose discrete lid and channel layers, it would have been obvious to one having ordinary skill in the art at the time of invention to separate the lid and channel layers of Craig, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (MPEP 2144.04, Section V, Part C)”. The cited section of MPEP refers to *In re Dulberg* for the proposition that separating an integral device into structural elements would be obvious “if it were considered desirable for any reason”. *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is “press fitted” and therefore not manually removable. The court held that “if it were considered desirable for any reason to obtain access to the end of [the prior art’s] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.”).

Thus, the Office once again relies on a legal precedent as a sole source of a rationale to modify Craig. However, such use was recently questioned by the Board of Patent Appeals in *Ex*

parte Granneman, 68 USPQ2d 1219 (B.P.A.I. 2003). The Board admonished the Office for applying a *per se* rule of obviousness without comparing the facts of the case:

The Examiner does not compare the facts in *Harza* with those in the present case and explain why, based on his comparison, the legal conclusion in the present case should be the same as that in *Harza*. Instead, the examiner relies upon *Harza* as establishing a *per se* rule that duplication of parts is obvious. As stated by the Federal Circuit in *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995), “reliance on *per se* rules of obviousness is legally incorrect and must cease.”

Ex parte Granneman, 68 USPQ2d 1219, 1220 (B.P.A.I. 2003)

The Board eventually reversed the Examiner on the ground that he had not explained why the prior art would have suggested to one of ordinary skill in the art the desirability of the modification, and therefore he had not established a *prima facie* case of obviousness of the appellant’s claimed invention. Even though *Ex parte Granneman* is a pre-*KSR* case, the principle that a legal precedent cannot be used as a sole rationale to modify a prior art reference is still valid.

In this case, Craig expressly teaches that a continuous foldable substrate is critically important for providing “precise alignment” of the microstructures with “extreme accuracy” (see Craig at col. 4, lines 33-37, emphasis added). Why, then, would it be desirable to remove this key inventive element? The Office’s proposed rationale of allowing “separate fabrication of the lid and channel layers, thereby increasing the scale and ease of production of such gas chromatograph columns” does not make any sense because it sacrifices the main benefit of Craig, i.e. accuracy of alignment, solely to match the blueprint of the present invention.

Moreover, a general statement that modifications of the prior art to meet the claimed invention would have been “‘well within the ordinary skill of the art at the time the claimed invention was made’” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP § 2143.01.IV; *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). The MPEP

makes it very clear that the question is not whether the skilled artisan would have been able to carry out the experiments at the time of the invention, but rather what objective reason would he/she have had to combine the teachings of the references. Therefore, Applicants respectfully maintain that a skilled artisan aiming to improve the chromatography column of Craig would have had no objective reason to split the continuous foldable substrate into discrete layers because such a modification would have deprived the device of Craig of its primary technical advantage, i.e., the accurate alignment of the microstructures.

Since all the remaining claims depend directly or indirectly on claim 1, the same basic reasoning applies. In summary, a person skilled in the art at the time of the invention would not have been motivated to combine the teachings of Craig and Goedert because Craig and Goedert disclose conceptually different configurations and because such a combination would clearly rob the device of Craig of its primary technical advantage. Accordingly, Applicants respectfully submit that the Office has failed to establish a case of *prima facie* obviousness and request that these rejections under 35 U.S.C. § 103(a) be withdrawn and the claims be passed to issue.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. **514572000500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 9, 2009

Respectfully submitted,

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